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(57) Abstract

A composition is provided for whitening a tooth in a dental arch, including at least 30 % by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5.KHSO_4.K_2SO_4$) in a slurry or in a dry form, wherein the composition does not cause damage visible to the naked eye to a soft tissue during a treatment period. A composition is also provided for whitening a tooth including at least 30 % by weight of potassium hydrogen peroxymonopersulfate ($2KHSO_5.KHSO_4.K_2SO_4$) in a slurry or dry form, wherein the composition does not include a peroxide bleaching agent. In another embodiment, a method is provided for whitening a tooth in a dental arch. The method includes (1) contacting the dental arch with a composition comprising at least 30 % by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5.KHSO_4.K_2SO_4$) in a slurry or in an aqueous solution, wherein the pH of said composition is adjusted from about pH=5.0 to about pH=8.5, and wherein the contacting does not cause damage visible to the naked eye to a soft tissue of the dental arch during a treatment period; and (2) removing the composition from the dental arch. In a further embodiment, a method is provided for whitening a tooth including contacting the tooth with a composition including at least 30 % by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5.KHSO_4.K_2SO_4$) in a slurry or in an aqueous solution, wherein the pH of the composition is adjusted to range from about 5.0 to about 8.5, and removing the composition comprising at least 30 % by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5.KHSO_4.K_2SO_4$). The method also includes contacting the tooth with a composition including a peroxide bleaching agent, wherein the agent generates hydrogen peroxide as 15 % or less by weight of the composition; and removing the composition including a peroxide bleaching agent. A kit is also provided for whitening teeth including a carrier means being compartmentalized to receive in close confinement therein one or more containers including a first container containing potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5.KHSO_4.K_2SO_4$) and an agent to adjust the pH from about 5.0 to about 8.5.

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COMPOSITION AND METHOD FOR WHITENING TEETH WITHOUT DAMAGING SOFT TISSUE

CROSS REFERENCE TO RELATED APPLICATION

This application claims priority from U.S. Provisional Application Serial No. 60/100,779, filed September 18, 1998, which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

The present invention relates to the field of dentistry, and specifically to the whitening of the teeth.

BACKGROUND OF THE INVENTION

Teeth generally become more darkly pigmented with age and exposure to materials such as tea and coffee, and it has long been a goal of dentistry to provide a means to safely and effectively reverse this darkening process. Historically there are two approaches to the problem. The first involves removing pigmentation that has adhered onto the surface of the teeth. The conventional techniques commonly use abrasives, sometimes augmented with solvents. While rapidly effective, these techniques have the disadvantage of only being able to remove external stains, leaving all internal pigmentation unchanged. Thus, the whitening effect is extremely limited.

A second technique involves a method of using oxidizing agents to penetrate into the tooth structure and bleach out the undesired pigmentation. The active agents are usually either weak solutions of carbamide peroxide or hydrogen peroxide. At present, the application of the whitening agent utilizes either custom or stock trays that are shaped to hold the bleaching agent against the teeth to be whitened. The trays are filled with gel or liquid peroxide, and worn for long periods

of time, sometimes even overnight. After a series of lengthy treatments, the teeth usually begin to show the desired whitening effect. The length of the treatment can be discouraging, and increases the cost.

While effective on both external and internal discolorations, one major problem encountered with the approach stems from the materials used. All of the aqueous solutions of peroxide ("wet" peroxides) begin to break down and lose effectiveness with time. Although this degradation is desirable while in use- since it is the reaction products that causes the bleaching effect- it is undesirable during shipping and storage. An attempt to overcome this limitation has been made by adding gelling agents such as Carbopol, Pemulan, and the like, to the urea peroxide solution. Although the gels extend the useful life of the peroxide, they also slow down its effectiveness during use. Some products cannot be shipped during certain times of the year or over weekends as they loose too much potency during the shipping period due to temperature variations. Thus, most of the products currently on the market require use within a short time after manufacture and often require refrigeration during storage.

While effective on external and internal discolorations, there is a major problem associated with the use of peroxides that stems from their mechanism of action. The two major pathways of action of the peroxides are through liberation of either hydroxyl free radicals or oxygen free radicals. In an environment with a pH lower than approximately 8 the oxygen free radical is generally the most active, while the hydroxyl free radical becomes most important in an alkaline environment above pH 8. In some studies these free radicals have been implicated as either carcinogens or co-carcinogens and the use of peroxide products has therefore been banned in many countries.

In an attempt to decrease the time needed for acceptable bleaching of teeth, techniques have been developed which feature the use of very strong peroxide mixtures with and without the use of radiant energy or heat to speed up the procedure. Unfortunately, these materials are extremely caustic and therefore require that the soft tissues be protected from contact. This is usually accomplished through the use of

either a rubber dam which is time consuming and uncomfortable for the patient or a "paint-on rubber dam" which is time consuming and often ineffective. In either case the patient risks burns if application of the barrier is imperfect and additional time must always be allotted to the procedure for this tedious but critical step.

In light of the forgoing, it is apparent that there is a need in the art for a method to simply and comfortably whiten teeth using materials that do not generate high concentrations of damaging free radicals, and that are less damaging to the soft tissue. It is thus desirable to develop new methods of whitening teeth that decrease or eliminate contact of the dental arches with peroxides, and that do not require the isolation of the teeth from the soft tissues.

SUMMARY OF THE INVENTION

In light of the foregoing, it is apparent that there is a need in the art to simply and comfortably whiten teeth with materials that may eliminate or lessen the period of treatment using peroxides.

Accordingly, in one embodiment, the present invention provides a composition for whitening teeth consisting of a therapeutically effective amount of a bleaching compound which is not of the peroxide class.

A composition is provided for whitening a tooth in a dental arch, including at least 30% by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) in a slurry or in a dry form, wherein the composition does not cause damage visible to the naked eye to a soft tissue during a treatment period.

A composition is provided for whitening a tooth including at least 30% by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) in a slurry or dry form, wherein the composition does not include a peroxide bleaching agent. In another embodiment, the composition includes potassium monopersulfate with a pH modifying agent such as, for example, tri-poly phosphate or tri-sodium phosphate.

In another embodiment, a method is provided for whitening a tooth in a dental arch. The method includes (1) contacting the dental arch with a composition

comprising at least 30% by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) in a slurry or in an aqueous solution, wherein the pH of said composition is adjusted from about pH=4.5 or 5.0 to about pH=8.5, and wherein the contacting does not cause damage visible to the naked eye to a soft tissue of the dental arch during a treatment period; and (2) removing the composition from the dental arch.

In a further embodiment, a method is provided for whitening a tooth including contacting the tooth with a composition including at least 30% by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) in a slurry or in an aqueous solution, wherein the pH of the composition is adjusted to range from about 5.0 to about 8.5, and removing the composition comprising at least 30% by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$). The method also includes contacting the tooth with a composition including a peroxide bleaching agent, wherein the agent generates hydrogen peroxide as 15% or less by weight of the composition; and removing the composition including a peroxide bleaching agent.

A kit is also provided for whitening teeth including a carrier means being compartmentalized to receive in close confinement therein one or more containers including a first container containing potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) and an agent to adjust the pH from about 5.0 to about 8.5.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a graph of the change in brightness of a stained artificial tooth after treatment with a 3.7 g Potassium hydrogen peroxymonopersulfate sulfate mixed with 1 ml of water yielding a pH of 3.1 including different amounts of peroxide. The results show a decreased brightness using compositions including 10% or more peroxide.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

It must be noted that as used herein and in the appended claims, the singular forms "a," "and," and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a tooth" includes a plurality of teeth and reference to "the compound" includes reference to one or more compounds and equivalents thereof known to those skilled in the art, and so forth.

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood to one of ordinary skill in the art to which this invention belongs. Although any methods, devices and materials similar or equivalent to those described herein can be used in the practice or testing of the invention, the preferred methods, devices and materials are now described.

All publications mentioned herein are incorporated herein by reference in full for the purpose of describing and disclosing the chemicals, materials, and methodologies which are described in the publications which might be used in connection with the presently described invention. The publications discussed throughout the text are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the inventor is not entitled to antedate such disclosure by virtue of prior invention.

The invention provides a composition for whitening teeth consisting of a therapeutically effective amount of a bleaching compound which is not of the peroxide class. A "bleaching compound" is any compound which has the ability of whitening teeth. "The peroxide class" refers to any compound whose main bleaching action is derived from the breakdown of peroxide ions such as hydrogen peroxide, carbamide peroxide, urea peroxide, sodium percarbonate, and perhydrol urea. Examples of bleaching compounds not of the peroxide class are potassium monopersulfate and ozone. By "therapeutically effective amount" is meant the quantity of bleaching agent, when placed in contact with the teeth of a subject according to the invention, necessary to whiten the teeth of the subject.

The bleaching agent employed is placed in a composition such that it will produce a strength in solution of at least 2% and can range up to a saturated solution.

One particularly useful active agent utilized in such compositions is formed from the combination of water and a potassium monopersulfate compound. A useful potassium monopersulfate compound is produced by Dupont under the trade name "Oxone" and consists of a combination of materials as shown below:

Potassium peroxymonosulfate	43%
Potassium bisulfate	23%
Potassium sulfate	29%
Potassium peroxidisulfate	3%
Magnesium carbonate	2%

Such a mixture in concentrated form will usually cause a burn to the soft tissues within ten to twenty minutes of exposure. This is primarily caused because of the highly acidic nature of the mixture. By regulating the acidity of the mixture, however, it is possible to create mixtures which do not cause visible irritation of the soft tissue within the therapeutic time periods needed for effective tooth whitening.

One great difficulty encountered in creating these acidity-regulated mixtures comes from the fact that many of the active agents used such as the monopersulfate ion are more stable in highly acidic mixtures. If the pH of the stable monopersulfate mixture is raised too high, above 5.0 for example, the monopersulfate ion becomes "blown off" and no longer is available for bleaching. Merely mixing a high pH solution or material into such a mixture in the usual fashion results in a rapid de-activation of the entire mixture. The result is a mixture that is gentle to the soft tissue, but relatively useless for tooth whitening. This occurs even if the final pH is low, because during the addition of the high pH material, the interface between the high pH material and the base mixture was locally too high.

One way around this problem is to fold into the monopersulfate mixture a material of relatively high pH, but which displays relatively low solubility. Thus the pH is raised gently and relatively slowly without pockets of high pH. The result is a mixture of a formulation having a raised pH which still contains a high concentration

of active monopersulfate ions. Such pH modifying agents include, for example, tri-poly phosphate or tri-sodium phosphate.

A composition is provided for whitening a tooth in a dental arch, including at least 30% by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) in a slurry or in a dry form, wherein the composition does not cause damage visible to the naked eye to a soft tissue during a treatment period. The composition can be used to whiten one tooth, or an entire dental arch. A "dental arch" includes a tooth and the surrounding gingiva of a subject. A subject is any mammal, preferably human.

Potassium hydrogen peroxymonopersulfate sulfate has the chemical formula $2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$, and is also known as "oxone." Potassium hydrogen peroxymonopersulfate sulfate is used in a wide variety of products and process, including pool and spa disinfectants, paper recycling process aids, microetchants for printed circuits, laundry bleaches, and denture cleansers. The physical properties of potassium hydrogen peroxymonopersulfate sulfate are known in the art. The pH of a 1-3% solution is 2.0-2.3, and is stable. Potassium hydrogen peroxymonopersulfate sulfate is very soluble and is stable at a low pH. Stability is affected by pH, so that at a pH of greater than 7.0 potassium hydrogen peroxymonopersulfate sulfate is less stable and can decompose. Potassium hydrogen peroxymonopersulfate sulfate is soluble as 256 g/liter at 20 °C. At concentrations above saturation potassium sulfate precipitates, but additional potassium monopersulfate can remain in solution, so that the attainable % active oxygen in solution can be increased. At 20°C the active oxygen in solution is 0.92 weight percent (wt%), and at 71°C the active oxygen in solution is 1.13 (wt%). One of skill in the art can readily determine the solubility of potassium hydrogen peroxymonopersulfate sulfate at different temperatures and the resulting weight percent of active oxygen.

Potassium hydrogen peroxymonopersulfate sulfate has a low order of toxicity, such that the approximate lethal dose for rats is 2250 mg/kg. It should be noted that even though potassium hydrogen peroxymonopersulfate sulfate has been

documented to have a low order of toxicity, manufacture's do not recommend taking potassium hydrogen peroxymonopersulfate sulfate internally.

A composition including potassium hydrogen peroxymonopersulfate sulfate can be prepared as a dry granular or powdered form. Alternatively, a composition can be prepared as a slurry or as an aqueous solution. As used herein, "slurry" generally means a watery mixture of insoluble materials or soluble materials wherein the soluble material is in such a high concentration that some of the material remains undissolved. A slurry or a dry form of the composition of the invention includes at least 30% by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) . Potassium hydrogen peroxymonopersulfate sulfate is soluble in water, and thus a solution for the treatment of the dental arches can be prepared from the composition as an aqueous solution.

In order to treat a tooth in a dental arch, the composition including at least 30% by weight of potassium hydrogen peroxymonopersulfate sulfate is applied to a dental arch. The compositions can be applied as a slurry or an aqueous solution, however, it has been discovered that better control can be achieved by first thickening up the liquid into the form of a gel, paste, foam, or the like. A liquid tends to run off the tooth and would have to be held in place using something like a sponge or cotton.

The composition of the invention includes at least 30% by weight of potassium hydrogen peroxymonopersulfate sulfate, and does not cause damage visible to the naked eye to a soft tissue during a treatment period. As used herein "soft tissue" means any component of the mouth, throat or dental arches that is not composed of bone and teeth. Thus the gums, tongue, lips, throat and soft palate are soft tissues. As used herein "damage" includes any visible destruction of the soft tissues. Examples of soft tissue damage include, but are not limited to burning, necrosis, laceration, tissue sluff and bleeding. As used herein, "visible" means anything visible to the naked eye under ample indoor illumination over the treatment period. The "treatment period" is the time that the composition is applied to the dental arch. In one embodiment, the treatment period is from about 5 to about 10 minutes. The treatment period can be repeated, so that the composition of the invention is

applied for more than one treatment period, wherein each treatment period lasts from about 5 to about 10 minutes. In one embodiment, four or five treatment periods are utilized, so that the total amount of time that the dental arches are exposed to the composition of the invention can be from about forty to about fifty minutes. Longer, single treatments are also applicable depending upon the mode and composition of application, thus it is envisioned that a single treatment can be about 5 to 10 minutes or about 10 to 40 minutes.

The composition of the invention can also include a pH adjusting agent sufficient to change the pH of the slurry or an aqueous solution prepared from said dry form of potassium hydrogen peroxymonopersulfate sulfate. In general the pH of the slurry or the aqueous solution will be from about pH= 5.0 to about pH=8.5 when it is applied to the dental arches. A "pH adjusting agent" is an acid, base, or buffer which can be used to change the concentration of hydrogen ions (the pH) in a formulation. In one embodiment, the agent to adjust the pH is sodium phosphate tripoly ($Na_5P_3O_{10}$). Other agents are known in the art and include, but are not limited to, tri-sodium phosphate, sodium tri-polyphosphate, and perborates, such as sodium perborate.

In one embodiment, the composition of the invention does not include a peroxide bleaching agent. A "peroxide bleaching agent" is a bleaching agent that generates hydrogen peroxide. In another embodiment, the composition of the invention includes a peroxide bleaching agent. Peroxide bleaching agents include, but are not limited to, hydrogen peroxide, carbamide peroxide, urea peroxide, sodium percarbonate, sodium perborate, calcium hydroxide, potassium chlorate, magnesium carbonate and perhydrol urea. In one embodiment, the peroxide bleaching agent is 15% or less by weight in the composition of the invention.

A surfactant can also be included in the composition of the invention. A "surfactant" is a substance which changes the nature of a surface, including water surface tension. In general, a surfactant lowers the surface tension of a liquid. Surfactants include, but are not limited to detergents, emulsifiers, penetrants, and wetting agents. Surfactants of use with in the composition of the invention include,

but are not limited to sodium lauryl sulfate, Pluronic 127® (poloxymer 407 or block co-polyol of ethyleneoxide and propylene oxide), Tween 20® (polyoxyethlyne (2) sorbitan monolaurate), Surfynal 485W® (ethoxylated 2,4,7,9-tetramethyl 5 decyn-4,7-diol), Pemulan® (acrylates 10-30 alkyla acrylate crosspolymer), and sodium dodcylbenensulfanate.

The composition of the invention can also include a whitening enhancer. A "whitening enhancer" is a material that is not capable of creating significant whitening effect on the teeth within a reasonable time frame on their own but which can augment the effect of other, more effective whitening agents. Specific, non-limiting examples of whitening enhancers include, but are not limited to ammonium persulfate, sodium persulfate, and potassium persulfate.

The composition of the invention can also include an agent for decreasing tooth sensitivity. An "agent for decreasing tooth sensitivity" is an agent that lowers the susceptibility of a tooth to a stimulation such as temperature or pressure. Ingredients to decrease tooth sensitivity include, but are not limited to potassium nitrate, citric acid, citric acid salts, sodium fluoride, and strontium chloride.

The composition of the invention can also include an optical brightener. An "optical brightener is a material such as a dye or pigment that absorbs electromagnetic energy of one portion of the spectrum and re-emits the energy as visible light in the blue portion of the spectrum. The absorbed electromagnetic energy is often in the ultra-violet range. The material can be incorporated into the structure of the tooth and the optical properties of the tooth are thus enhanced. When energy is emitted in the blue portion of the spectrum the blue light given off by the tooth is perceived as having a whitening effect. An additional benefit of optical brighteners is that they absorb energy, such as ultra-violet energy. Thus, these materials can protect the tissues from effects of exposure to the energy, such as protecting the soft tissues from the effects of ultra-violet light. Optical brighteners include, but are not limited to, Tinopal PT® (CAS No. 16470-24-9), Eastobright® (2,2'-(1,2-ethenediyl)bis(4,1-phenylene)bisbenzoxazole), and Uvitex-OB® (CAS No. 7128-64-5).

The composition of the invention can also include a texturing agent, such as a gelling agent. A "texturing agent" is an agent which provides a texture that is detectable by a subject. "Texturing agents" include, but are not limited to Carbopol, carboxymethyl cellulose, hydroxyethyl cellulose, gum arabic, sodium polyacrylate, potassium polyacrylate, silicon dioxide, fumed silicon dioxide, sodium polyacrylamide, aluminum silica, and fumed alumina silica. In one embodiment, the composition can include a gelling agent. A "gelling agent" is a agent which forms a semisolid suspension of small inorganic or large organic molecules upon addition of an aqueous solution. The aqueous solution interpenetrates the inorganic or large organic molecules in order to form the gel. Specific, non-limiting examples of a gelling agent are an alpha starch, an agar, hydroxyethyl cellulose, mangrot seed, hydroxymethyl cellulose, sodium polyacrylate, sodium polyacrylamide, poly-N-vinylpyrrolidone, poly-vinyltoluenesulfonate, poly-sulfoethyl acrylate, poly-2-hydroxyethyl acrylate, poly-vinylmethyloxazolidinone, hydrolyzed polyacrylamide, polyacrylic acid, copolymers of acrylamide and acrylic acid and alkali metal salts of such of the polymers that contain sulfonate or carboxylate groups.

The composition of the invention can further include a humectant. A "humectant" is a substance that absorbs and promotes the retention of moisture from the air. Suitable humectants include, but are not limited to glycerine and propylene glycol.

A material to enhance the conversion of energy from one form to another can also be included in the composition of the invention. In one embodiment, the material converts light to heat. A material that converts light energy in the visible spectrum of between 400 and 700 nm to heat is of use in the composition of the invention. Without being bound by theory, when a peroxide bleaching agent is included in the composition, the optical energy can accelerate the production of free radical production of hydrogen peroxide. In one embodiment, the material converts ultraviolet light to heat. In another embodiment, the material converts visible light to heat. Examples of materials which can convert light of specific wavelengths to heat include, but are not limited to beta carotene, phenothalein, guinea green, red

aluminum lake, benzoil peroxide and titanium dioxide. Some materials such as benoin make others such as benzoil peroxide more light-sensitive. Another example of a material that can convert light to heat and which can be useful in a peroxide-containing bleaching mixture is camphor quinone or bornanedione.

The composition of the invention can also include a palliative ingredient for periodontal tissues. Examples of such ingredients include, but are not limited to aloe, eugenol, corticosteroid and vitamin E. Agents that protect the soft tissues can also be included in the composition of the invention. These agents include, but are not limited to ascorbic acid, para amino benzoic acid, melatonin, and aloe vera. Pigments, sweeteners, colors, and flavors may also be incorporated into the composition.

The composition can also include an agent for administering fluoride, such as a fluorine providing salt, which can prevent cavities. Such materials are characterized by their ability to release fluoride ions in water. Agents for administering fluoride include, but are not limited to, inorganic metal salts such as sodium fluoride, potassium fluoride, and tin fluoride such as stannous fluoride or stannous chlorofluoride, sodium fluorosilicate, ammonium fluorosilicate and sodium monofluorophosphate.

A method for whitening a tooth in a dental arch is also provided. The method includes contacting a dental arch with a composition including at least 30% by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) in a slurry or in an aqueous solution, wherein the pH of said composition is adjusted from about pH=5.0 to about pH=8.5 for a treatment period. The contact of the composition including at least 30% by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) does not cause damage visible to the naked eye to a soft tissue of the of a soft tissue of the mouth or a dental arch during the treatment period.

Any number of methods of administering or using the compositions of the invention are applicable and known in the art, so long as the composition comes in contact with the tooth or tissue target

The composition of the invention is then removed from the dental arch. Removal can be by any means known to one of skill in the art. For example, the composition can be removed by rinsing with water or another aqueous solution such as a mouthwash. The composition can be removed by contacting the dental arch with an absorbent material such as cotton gauze or a soft cloth, suitable to absorb or wipe away the composition. Another method for removing the composition can be through the use of a suction or vacuum which is used to aspirate or remove the composition from the dental arch.

In the method of the invention a composition including at least 30% by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) is applied for a treatment period. The treatment period is from about 5 to about 10 minutes. The treatment period can be repeated, so that the composition of the invention is applied for more than one treatment period, wherein each treatment period lasts from about 5 to about 10 minutes. The composition of the invention can be removed between treatment periods, reapplied or left in place. In one embodiment, four or five treatment periods are utilized, so that the total amount of time that the dental arches are exposed to the composition of the invention is from about twenty to about fifty minutes.

In one embodiment, the composition includes at least 30% by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) and includes a material to enhance the conversion of energy from one form to another is treated with an energy source. In one embodiment, the material that enhances the conversion of energy from one form to another is a material that converts light energy to heat. The light can be light in the visible spectrum of between 400 and 700 nm as well as light from the non-visible spectrum (e.g., the infrared spectrum). Light energy is applied to the composition including a material that converts light to heat in order to produce heat. The application of light energy to the composition can be maintained for an entire treatment period, or may be applied prior to the treatment period. In general energy will be applied for at least three minutes, and may be applied for the entire treatment period. The energy may also be applied intermittently. Most

normally, the energy would be applied to one tooth for a short period of time, and then to the next tooth until all are treated. The series can be repeated if desired. It is possible, however, to use a source of energy that covers multiple teeth. In addition, a continuous application of energy can also be used. It is worth noting that even in the absence of a specific material to convert light to heat, the ingredients will react faster or more effectively in the presence of an increase in temperature. In addition, by raising the temperature of the aqueous solution, the solubility of the oxone is increased, which in turn results in a solution of higher concentration and increased effectiveness. Thus, in one specific, non-limiting example, the composition includes a material that converts light to heat. The composition is therefore treated with light prior to the treatment, or intermittently or continuously during the treatment of a dental arch.

A method is also provided for whitening a tooth, including contacting the tooth with a composition comprising at least 30% by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) in a slurry or in an aqueous solution, wherein the pH of said composition is adjusted to range from about 5.0 to about 8.5, and subsequently removing the composition comprising at least 30% by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$). The tooth is also contacted with a composition comprising a peroxide bleaching agent which generates hydrogen peroxide as 15% or less by weight of said composition, and removing said composition comprising said peroxide bleaching agent. The tooth can be contacted with the peroxide bleaching composition prior to, subsequent to, or simultaneously with the contact of the tooth with the composition including at least 30% by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) . In one embodiment, the tooth is contacted with a composition including at least 30% by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) in a slurry or in an aqueous solution, wherein the pH of said composition is adjusted to range from about 5.0 to about 8.5, and/or the tooth is contacted with a peroxide bleaching agent which generates hydrogen peroxide as 15% or less by weight of said composition. By

repeatedly contacting the tooth with the composition including at least 30% by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) an additional whitening effect is achieved.

The materials for use in the assay of the invention are ideally suited for the preparation of a kit. Such a kit may comprise a carrier means containing one or more container means such as vials, tubes, and the like, each of the container means including one of the separate elements to be used in the method. The kit includes a carrier means being compartmentalized to receive in close confinement therein one or more containers. In one embodiment, a first container is included in the kit which contains potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) and an agent to adjust the pH from about 5.0 to about 8.5. In another embodiment, a first container is included in the kit which contains potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) and a second container is included in the kit which contains an agent to adjust the pH of a solution or slurry prepared from potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) from about 5.0 to about 8.5 (*e.g.*, sodium phosphate tripoly ($Na_5P_3O_{10}$)). The kit can also include a container which contains a peroxide bleaching agent.

The following examples are intended to illustrate but not to limit the invention in any manner, shape, or form, either explicitly or implicitly. While they are typical of those that might be used, other procedures, methodologies, or techniques known to those skilled in the art may alternatively be used. For example, it will be recognized that the combination of compounds present in the compositions of the invention are high. Accordingly, although the examples below present exemplary compositions, these compositions can include any number of additional compounds such as flavoring agents, gelling agents, combinations of peroxides, and other combinations recognized by those of skill in the art.

EXAMPLES

EXAMPLE 1

A custom fabricated outer layer of a dental tray was produced by vacuuforming a sheet of 0.20 inch plastic to a plastic model of a subjects teeth. The tray was trimmed to cover the teeth and very little of the surrounding tissue. A dry composition was prepared including:

1.5 gm of Oxone, a mixture including:

Potassium peroxymonosulfate	43%
Potassium bisulfate	23%
Potassium sulfate	29%
Magnesium carbonate	2%

0.05 gm fumed aluminum silica

0.5 gm of Pemulen (Union Carbide) (Note: Pemulen is acrylates/C10-30 Alkyl Acrylate cross polymer, a high molecular weight co polymer of acrylic acid and a long chain alkyl methacrylate cross-linked with polyalkenyl ethers of polyalcohols)

flavoring (sufficient for a pleasant taste)

Just prior to use, 6 ml of water was added to the dry composition. The pH was adjusted to approximately 7.5 using sodium phosphate tripoly ($Na_5P_3O_{10}$). The mixture was stirred for 30 seconds. One-third of the wetted composition was placed into the custom fabricated tray and the tray was subsequently placed over a subject's teeth. Any excess of the mixture that was extruded from the tray was immediately removed. After 90 minutes, the tray was removed. A visible amount of whitening of the subject's teeth had occurred. This whitening was approximately equal to 2-3 weeks of daily use of an over the counter tooth whitening paste.

EXAMPLE 2

A dry powdered mixture was prepared in the following proportions:

1.5 gm of Oxone, a mixture including:

Potassium peroxymonosulfate	43%
Potassium bisulfate	23%
Potassium sulfate	29%
Magnesium carbonate	2%

2.24 gm tripoly phosphate

0.1 gm fumed aluminum silica

0.5 gm of Permulen (Union Carbide)

0.3 gm potassium nitrate

sufficient flavoring to impart a pleasant taste and color.

A toothbrush was dipped into the powder to coat the brush. Upon making contact with the moisture in the toothbrush and with the subject's saliva the whitening agent became active. A subject brushed their teeth using the composition; the procedure was repeated three times in three minutes. At the end of fifteen sessions a visible difference was evident in the brightness of the teeth.

EXAMPLE 3

A mixture of 3 parts potassium monopersulfate compound such as produced by DuPont under the trade name Oxone was mixed with 2 parts tri-sodium phosphate into a slurry with a solution that was composed of 10 parts water to 4 parts glycerin and placed on a human tooth for a period of 30 minutes. No protection of the soft tissue was used. At the end of 20 minutes the mixture was removed from the teeth and the teeth were rinsed with fresh water. The amount of whitening exhibited was approximately equal to that expected from a two-week regimen of wearing custom trays with peroxide gels fro two weeks.

EXAMPLE 4

A slurry was made as in Example 1 except that tin place of plain water, a solution of water and ozone in a concentration of 3-4% was mixed and applied to the tooth. As the mixture began to dry it was stirred on the tooth with a small sable paintbrush that had been dipped into the ozone solution. The results of this treatment were even more dramatic than that of Example 3.

EXAMPLE 5

Various mixtures of agents listed above were placed on stained bovine teeth and the brightness of the teeth were measured both before and after a five minute exposure to the agents. The table below list some of the combinations tested and the results. A higher delta number indicates a greater amount of change in brightness of the substrate as a result of the exposure:

OXONE	K2S2O8	Gelling Agent	Optical Brightner	Na-Perborate	Smoothing agent	Surfactant	Exposure to Intense light	Na-Fl	Oxyquinone	Delta (Change in brightness)
y							y	y		4
y										5
y						y		y		5
y	y	y	y		y	y			y	7
y		y			y					7
y						y				8
y				y		y				9
y			y					y		9
y								y		10
y				y						10
y	y	y	y				y	y		11
y		y						y		11
y		y	y				y	y	y	12
y								y		12
y		y	y				y	y		13

y	y	y	y
			y
y	y	y	
			y
		y	
		y	y
y	y	y	y
			y
y	y	y	y
		y	y
		y	y
y	y	y	y
13	14	14	16

It is to be understood that while the invention has been described in conjunction with the detailed description thereof, the foregoing description is intended to illustrate and not limit the scope of the invention, which is defined by the scope of the appended claims. Other aspects, advantages, and modifications are within the scope of the following claims.

What is claimed is:

1. A composition for whitening a tooth in a dental arch, comprising at least 30% by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) in a slurry or in a dry form, wherein said composition does not cause damage visible to the naked eye to a soft tissue during a treatment period.

2. The composition of claim 1, further comprising a pH adjusting agent sufficient to adjust the pH of said slurry or an aqueous solution prepared from said dry form of said composition from about pH= 5.0 to about pH=8.5.

3. The composition of claim 1, further comprising a pH adjusting agent sufficient to adjust the pH to about 4.5 to 5.0.

4 The composition of claim 2, wherein said agent to adjust the pH is sodium phosphate tripoly ($Na_5P_3O_{10}$) or trisodium phosphate.

5. The composition of claim 1, further comprising a peroxide bleaching agent, wherein said agent generates hydrogen peroxide as 15% or less by weight.

6. The composition of claim 5, wherein said peroxide bleaching agent is selected from the group consisting of hydrogen peroxide, carbamide peroxide, urea peroxide, sodium percarbonate, sodium perborate, calcium hydroxide, potassium chlorate, magnesium carbonate and perhydrol urea.

7. The composition of claim 6, wherein said bleaching agent is carbamide peroxide.

8. The composition of claim 1, further comprising a surfactant.

9. The composition of claim 8, wherein said surfactant is selected from the group consisting of sodium lauryl sulfate, Pluronic 127®, Tween 20®, Surfynal 485W®, Pemulan®, and sodium dodcylbenensulfanate.

10. The composition of claim 1, further comprising a whitening enhancer.

11. The composition of claim 1, wherein said whitening enhancer is selected from the group consisting of ammonium persulfate, sodium persulfate, and potassium persulfate.

12. The composition of claim 1, further comprising an agent to decrease tooth sensitivity.

13. The composition of claim 12, wherein said agent to decrease tooth sensitivity is selected from a member of the group consisting of potassium nitrate, citric acid, citric acid salts, sodium fluoride, and strontium chloride.

14. The composition of claim 1, further comprising an optical brightener.

15. The composition of claim 14, wherein said optical brightener is selected from the group consisting of Tinopal PT®, Eastobright®, and Uvitex-OB®.

16. The composition of claim 1, further comprising a texturing agent.

17. The composition of claim 16, wherein said texturing agent is selected from the group consisting of Carbopol, carboxymethyl cellulose, hydroxyethyl cellulose, gum arabic, sodium polyacrylate, potassium polyacrylate, silicon dioxide, fumed silicon dioxide, aluminum silica, and fumed alumina silica.

18. The composition of claim 1, further comprising a humectant.

19. The composition of claim 1, wherein said humectant is selected from the group consisting of glycerine and propylene glycol.

20. The composition of claim 1, further comprising a material to enhance the conversion of energy from one form to another.

21. The composition of claim 20, wherein said material to enhance the conversion of energy converts light to heat.

22. The composition of claim 21, wherein said material to enhance the conversion of energy is selected from the group consisting of beta carotene, phenothalein, guinea green, red aluminum lake, benzoil peroxide and titanium dioxide.

24. The composition of claim 1, further comprising an agent to protect the soft tissue.

25. The composition of claim 23, wherein said agent is selected from the group consisting of ascorbic acid, para amino benzoic acid, melatonin and aloe vera.

26. The composition of claim 1, further comprising a flavoring agent.

27. The composition of claim 1, wherein said treatment period is from about five to 10 minutes.

28. The composition of claim 1, wherein said treatment period is from about 10 to forty minutes.

29. The composition of claim 1, further comprising a therapeutically effective amount of ozone.

30. A composition for whitening a tooth comprising at least 30% by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) in a slurry or dry form, wherein said composition does not include a peroxide bleaching agent.

31. A method for whitening a tooth in a dental arch, comprising:

(1) contacting said dental arch with a composition comprising at least 30% by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) in a slurry or in an aqueous solution, wherein the pH of said composition is adjusted from about pH=4.5 to about pH=8.5, and wherein said contacting does not cause damage visible to the naked eye to a soft tissue of the dental arch during a treatment period; and

(2) removing said composition from said dental arch.

32. The method of claim 29, wherein said treatment period is from about 5 to about 10 minutes.

33. The method of claim 29, wherein said treatment period is from about 10 to 40 minutes.

34. The method of claim 29, wherein said removing is by rinsing said dental arch with a rinsing solution.

35. The method of claim 29, further comprising repeating said contacting step (1).

36. The method of claim 29, further comprising

treating said composition with an energy source.

37. The method of claim 29, wherein said energy is selected from the group consisting of light and heat.

38. A method for whitening a tooth, comprising:

(1) contacting said tooth with a composition comprising at least 30% by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) in a slurry or in an aqueous solution, wherein the pH of said composition is adjusted to range from about 4.5 to about 8.5;

(2) removing said composition comprising at least 30% by weight of potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) ;

(3) contacting said tooth with a composition comprising a peroxide bleaching agent, wherein said agent generates hydrogen peroxide as 15% or less by weight of said composition; and

(4) removing said composition comprising said peroxide bleaching agent.

39. The method of claim 36, further comprising repeating said contacting step (1) and said removing step (2).

40. A kit for whitening teeth comprising a carrier means being compartmentalized to receive in close confinement therein one or more containers comprising a first container containing potassium hydrogen peroxymonopersulfate sulfate ($2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) and an agent to adjust the pH from about 5.0 to about 8.5.

41. The kit of claim 38, wherein said agent to adjust pH is sodium phosphate tripoly ($Na_5P_3O_{10}$).

42. The kit of claim 38, further comprising a container containing a peroxide bleaching agent.

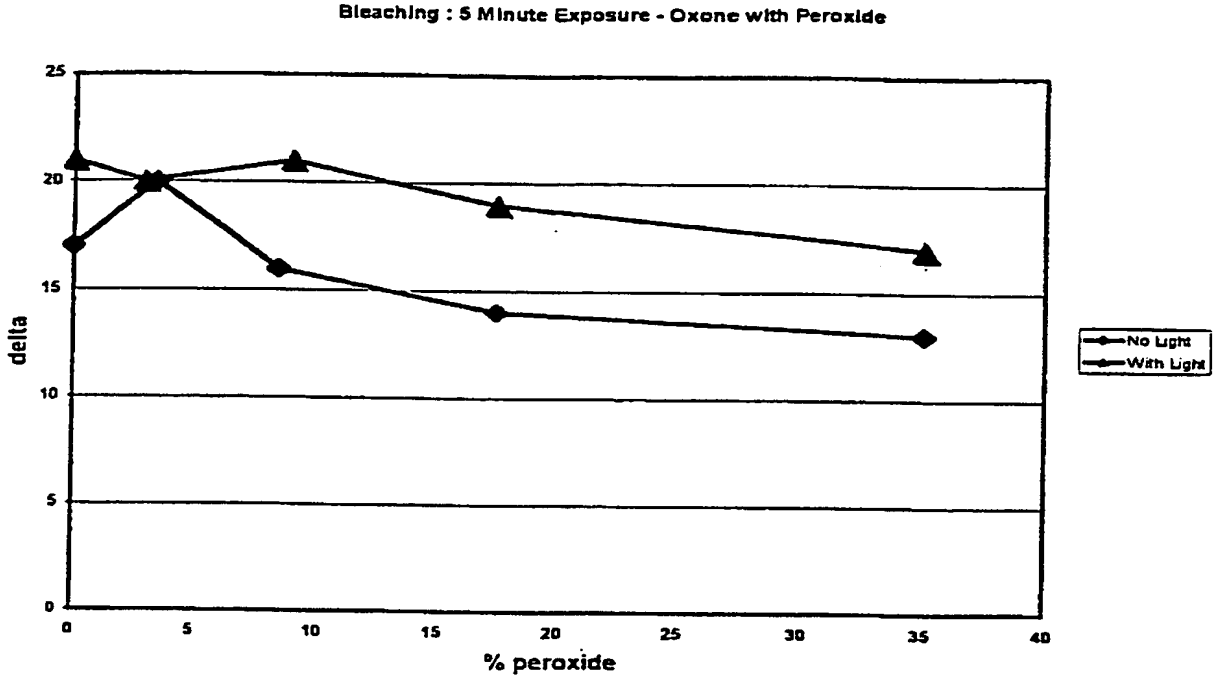
Bleaching : 5 Minute Exposure - Oxone with Peroxide
delta
% peroxide
No Light
With Light
0
5
10
15
20
25
30
35
40

FIGURE 1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/21371

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A 6 1K 7/20
US CL :424/53
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/53

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

(703) 305-3230

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,575,654 A (FONTENOT) 19 November 1996, See column 5, lines 9, 10, column 8, line 10, column 5, line 12	12
X	US 5,645,428 A (, YARBOROUGH) 08 July 1997, see column 2, line 58, claim 24.	6, 8, 9, 16, 17, 18, 19, 30 TO 42
X	US 5,713,738 A (YARBOROUGH) 03 February 1998, see column 5, line 9, claim 44.	TO 6, 8, 9, 16, 17, 18, 19, 30 TO 42
Y	US 5,766,574 A (L. CHRISTINA-BECK ET AL) 16 June 1998, see column 5, lines 18-28. Column 6, lines 41-43 and column 6, line 39.	12
Y	US 3,988,433 A (J. BENEDICT) 26 October 1976 column 7, lines 39-50.	6, 42

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

(703)

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 JANUARY 2000	10 FEB 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No.	Authorized officer Shep Rose Telephone No.

Form PCT/ISA/210 (second sheet)(July 1992)★

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/21371

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,279,816 A (J. CHURCH ET AL) 18 JANUARY 1994 SEE ENTIRE DOCUMENT.	6, 42
T, P	US 5,851,512 A (D. FISCHER) 22 December 1998 see entire document.	12
T, P	US 5,855,870 A (D. FISCHER) 05 01 1999 see entire document.	x

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